such as shape, color, coating, scoring, and National Drug Code; and

- (4) Special handling and storage conditions.
- (1) Animal Pharmacology and/or Animal Toxicology. In most cases, the labeling need not include this section. Significant animal data necessary for safe and effective use of the drug in humans shall ordinarily be included in one or more of the other sections of the labeling, as appropriate. Commonly for a drug that has been marketed for a long time, and in rare cases for a new drug, chronic animal toxicity studies have not been performed or completed for a drug that is administered over prolonged periods or is implanted in the body. The unavailability of such data shall be stated in the appropriate section of the labeling for the drug. If the pertinent animal data cannot be appropriately incorporated into other sections of the labeling, this section may be used.
- "Clinical Studies" and "Ref-(m) erences". These sections may appear in labeling in the place of a detailed discussion of a subject that is of limited interest but nonetheless important. A reference to a specific important clinical study may be made in any section of the format required under §§ 201.56 and 201.57 if the study is essential to an understandable presentation of the available information. References may appear in sections of the labeling format, other than the "Clinical Studies" or "References" section, in rare circumstances only. A clinical study or reference may be cited in prescription drug labeling only under the following conditions:
- (1) If the clinical study or reference is cited in the labeling in the place of a detailed discussion of data and information concerning an indication for use of the drug, the reference shall be based upon, or the clinical study shall constitute, an adequate and well-controlled clinical investigation under §314.126(b) of this chapter.
- (2) If the clinical study or reference is cited in the labeling in the place of a detailed discussion of data and information concerning a risk or risks from the use of the drug, the risk or risks shall also be identified or discussed in

the appropriate section of the labeling for the drug.

[44 FR 37462, June 26, 1979, as amended at 55 FR 11576, Mar. 29, 1990; 59 FR 64249, Dec. 13, 1994; 62 FR 45325, Aug. 27, 1997; 63 FR 66396, Dec. 1, 1998]

§ 201.58 Requests for waiver of requirement for adequate and well-controlled studies to substantiate certain labeling statements.

A request under §201.57(b)(2)(ii), (c)(2), (c)(3)(i), (c)(3)(v), (f)(9), and (g)(4) for a waiver of the requirements of §314.126(b) of this chapter shall be submitted in writing as provided in §314.126(b) to the Director, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20587, or, if applicable, the Director, Center for Biologics Evaluation and Research, 8800 Rockville Pike, Bethesda, MD 20892. The waiver shall be granted or denied in writing by such Director or the Director's designee.

[55 FR 11576, Mar. 29, 1990]

§ 201.59 Effective date of §§ 201.56, 201.57, 201.100(d)(3), and 201.100(e).

- (a) On and after December 26, 1979, no person may initially introduce or initially deliver for introduction into interstate commerce any drug to which §\$ 201.56, 201.57, 201.100(d)(3) apply unless the drug's labeling complies with the requirements set forth in the regulations, with the following exceptions:
- (1) If the drug is a prescription drug that is not a biologic and not subject to section 505 of the act (21 U.S.C. 355), and was not subject to former section 507 of the act (21 U.S.C. 357, repealed 1997), §§ 201.56, 201.57, and 201.100(d)(3) are effective on April 10, 1981.
- (2) If the drug is a prescription drug that on December 26, 1979 is (i) a licensed biologic, (ii) a new drug subject to an approved new drug application or abbreviated new drug application under section 505 of the act or (iii) an antibiotic drug subject to an approved antibiotic form, §§ 201.56, 201.57, and 201.100(d)(3) are effective on the date listed below for the class of drugs to which the drug belongs. Dates are also listed below for the submission of supplemental applications, amendments, and license changes.

§ 201.59

(3) If the drug is approved after December 26, 1979 but is a duplicate of a drug approved on or before that date (for example, a drug approved under an abbreviated new drug application or an antibiotic form), §§ 201.56, 201.57, and

201.100(d)(3) are effective on the date listed below for the class of drugs to which the drug belongs. Dates are also listed below for the submission of supplemental applications, amendments, and license changes.

Nov. 1, 1982	Effective	Revised label- ing due	Drug class	Mail routing code	
Do. do			Biologics		
Do do Skin test antigens HFB-240 Nov. 1, 1982/Do Nov. 1, 1980/Do HFB-240 Nov. 1, 1982/Do Nov. 1, 1982/Do Nov. 1, 1980/Do Antiarrhythmics HFD-110 HFD-110 Do	Nov. 1, 1982	Nov. 1, 1980		HFB-240	
Nev. 1, 1982	Nov. 1, 1982 ¹ Do Do	Nov. 1,1980 ² dodo	Skin test antigens	HFB-240 HFB-240 HFB-240	
Nov. 1, 1982	D0	do		NFB-240	
Do do Replenishers and regulators of electrolytes and water balance HFD-160 HFD-160, and HFD-160 Do do Anticonvulsants HFD-160 Do do Adrenal corticosteroids HFD-510 and HFD-150 Do do Scabicides Do Do do Pediculicides HFD-520 Do do General anesthetics HFD-520 Do do Decr. 1, 1982 Do Do Do do Dermatologics Do Do Jan. 1, 1983 Jan. 1, 1981 Jan. 1, 1983 Jan. 1, 1983 HFD-520 Do do Dermatologics Do Do Feb. 1, 1983 Feb. 1, 1983 Anticholinergics Do Do Do Do do Anticholinergics Do	New Drugs and Antibiotic Drugs				
Do do Adrenal corticosteroids HFD-510 and HFD-150 Do do Scabicides Do Do do Scabicides Do Do do Pediculicides Do Do do Arnivirals HFD-520 Dec. 1, 1982 Dec. 1, 1980 HFD-520 Do do Arnivirals HFD-520 Jan. 1, 1983 Jan. 1, 1981 Dematologics Do Do do do Do Feb. 1, 1983 Feb. 1, 1981 Anticholencerics Do Do do do Anticholenergics Do Do do Narcotic antagonists HFD-110 Do do Anticholenergics Do Do do Anticyolotics/antimarics Do Do do Anticyolotics/antimarics Do Do do Anticyolotyolotics/antimarics Do Do do Anticyolotyolotics/antimarics Do </td <td></td> <td></td> <td></td> <td>HFD-110, HFD-510, and</td>				HFD-110, HFD-510, and	
Do do Aminoglycosides HFD-520 Do					
Do do Scabicides Do. Do do General anesthetics HFD-160 Dec. 1, 1982 Dec. 1, 1982 Dec. 1, 1983 Jan. 1, 1981 Antivirals HFD-520 Do Jan. 1, 1983 Jan. 1, 1981 Glaucoma ophthalmics HFD-520 Do Jo Do Do Do Feb. 1, 1983 Feb. 1, 1981 Topical otics Do Do Jo Jo Do Do Do Jo Jo Anticholinergics Do Do Jo Jo Narcotic antagonists HFD-120 Do Jo Jo Antichol antagonists Do Do Jo Anticolor antagonists Do Do					
Do do Pediculicides Do Dec. 1, 1982					
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Do do Dermatologics Do. Jan. 1, 1983 Jan. 1, 1981 Jan. 1, 1981 HFD-520 Feb. 1, 1983 Feb. 1, 1981 Topical otics do Do do Antispasmodics do Do do Diuretics do Do do Narcotic antagonists do Do do Alcohol antagonists do Do do Androgens do Do do Anabolic steroids do Do do Anthelmintics do Do do Anthelmintics do Do do Anthelmintics do Mar. 1, 1983 Apr. 1, 1983 Apr. 1, 1981 Apr. 1, 1981 Apr. 1, 1981 Apr. 1, 1983 Apr. 1, 1981 Caplaosporins de May 1, 1983 May 1, 1981 Caplaosporins de Do do Hypothalamic hormones de Do do					
Jan. 1, 1983					
Do					
Feb. 1, 1983 Feb. 1, 1981 Antispasmodics HFD-110 Do				_	
Do do Anticholinergics Do. Do					
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Nov. 1, 1983 Nov. 1, 1981 Blood glucose regulators (except sulfonylureas) HFD-510					
				HFN-130	

Food and Drug Administration, HHS

Effective	Revised label- ing due	Drug class	Mail routing code
Nov. 1, 1983	Nov. 1, 1981	Drugs indicated for parenteral nutrition	HFD-510 and HFD-160
Do	do	Drugs indicated for enteral nutrition	Do.
Do	do	Miscellaneous ophthalmics	HFD-520
Do	do	Immunomodulators	HFD-150
Dec. 1, 1983	Dec. 1, 1981	Anticoagulants	HFD-110
Do	do	Thrombolytics	Do.
Do	do	Drugs indicated for acid peptic disorders	Do.
Do	do	Antidepressants	HFD-120
Do	do	Drugs indicated for skeletal muscle hyperactivity	Do.
Do	do	Sulfonamides and related sulfa compounds	HFD-520
Do	do	Dental preparations	HFD-160
an. 1, 1984	Jan. 1, 1982	Miscellaneous antibacterials	HFD-520
			HFD-520 HFD-510
eb. 1, 1984	Feb. 1, 1982	Drugs indicated for infertility	
Do	do	Thyroids	Do.
Do	do	Antithyroids	Do.
Do	do	Polymyxins	HFD-520
Do	do	Antineoplastics	HFD-150
/lar1, 1984	Mar. 1, 1982	Urinary tract stimulants	HFD_110
Do	do	Urinary tract relaxants	Do.
Do	do	Antimigraine	HFD-120
		Antimycobacterials (including antileprosy)	HFD-520
Do	do	Adjuncts to anethesia	HFD-160
Apr. 1, 1984	Apr. 1, 1982	Antianginals	HFD-110
Do	do	Laxatives	Do.
Do	do	CNS stimulants	HFD-120
Do	do	Anorexiants	Do.
Do	do	Chloramphenicol and derivatives	HFD-520
May 1, 1984	May 1, 1982	Drugs indicated for vertigo/motion sickness/vomiting	HFD-120
Do	do	Antidiuretics	HFD-510
Do	do	Contraceptives	Do.
Do	do	Macrolides	HFD-520
Do	do	Lincosamides	Do.
Do	do	Antiarthritics	HFD-150
Do	do	Antitussives	HFD-160
Do	do	Expectorants	Do.
Do	do	Inhalants	Do.
lune 1, 1984	June 1, 1982	Urinary tract antiseptics	HFD-520
uly 1, 1984	July 1, 1982	Chelating agents/heavy metal antagonists	HFD-110
Do	do	All other gastrointestinal drugs	HFD-110
Do	do	Antianxiety	HFD-110
Do	do	Drugs indicated for myasthenia gravis	HFD-120
Do	do	All other antiinfective drugs	HFD-520
Do	do	Bronchodilators/antiasthmatics	HFD-160
Nug. 1, 1984	Aug. 1, 1982	Estrogens	HFD-510
Do	do	Uterine stimulants	HFD_510
Do	do	Uterine relaxants	Do.
Sept. 1, 1984	Sept. 1, 1982	Drugs indicated for hypotension and shock	HFD-110
Oct. 1, 1984	Oct. 1, 1982	All other cardiac drugs	HFD-110
Do	do	Nasal decongestants	HFD-160
lov. 1, 1984	Nov. 1, 1982	All other prescription drugs.	1

(b) Section 201.100(e) is effective April 10, 1981.

[45 FR 32552, May 16, 1980, as amended at 46 FR 7272, Jan. 23, 1981; 49 FR 14331, Apr. 11, 1984; 50 FR 8995, Mar. 6, 1985; 55 FR 11576, Mar. 29, 1990; 64 FR 400, Jan. 5, 1999]

Subpart C—Labeling Requirements for Over-the-Counter Drugs

SOURCE: 41 FR 6908, Feb. 13, 1976, unless otherwise noted.

§201.60 Principal display panel.

The term principal display panel, as it applies to over-the-counter drugs in package form and as used in this part, means the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale.

¹Except the effective date for all biological products reviewed generically by the advisory panel is 30 months after a final order is published under 21 CFR 601.25(g).

²Except the due date for all biological products reviewed generically by the advisory panel is 6 months after a final order is published under 21 CFR 601.25(g).